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UNITED STATES PATENT & TRADEMARK OFFICE

Re: Application of: Wolfgang FLEISCHER and Karin REIMER
Serial No.: To Be Assigned
Filed: Simultaneously Herewith
For: **PREPARATIONS FOR THE APPLICATION OF
ANTI-INFLAMMATORY, ESPECIALLY
ANTISEPTIC AGENTS AND/OR AGENTS
PROMOTING THE HEALING OF WOUNDS, TO
THE LOWER RESPIRATORY TRACT**

LETTER RE: PRIORITY

Box: PCT
Assistant Commissioner for Patents
Washington, D.C. 20231

November 27, 2000

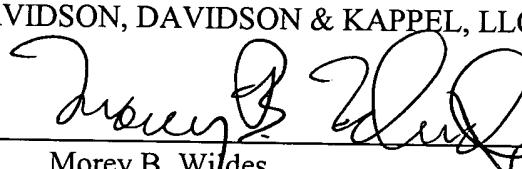
Sir:

Applicants hereby claim priority from United States Application No. 60/086,895 filed May 27, 1998.

Respectfully submitted,

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EP99/3681 June 08, 1999

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 APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A
 FILING DATE UNDER 35 USC 111.

APPLICATION NUMBER: 60/086,895**FILING DATE:** *May 27, 1998**09/701450*

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Assistant Commissioner of Patents
Washington, D.C. 20231

Atty. Docket No.: P62107US0

Sir:

Transmitted herewith for filing is a **PROVISIONAL APPLICATION OF**

Dr. Wolfgang FLEISCHER residing at
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-and-

Dr. Karen REIMER residing at
Im Rehwinkel 12, D-65582 Hambach, GERMANY

for POVIDONE IODINE FOR THE ADMINISTRATION VIA THE UPPER AND
LOWER RESPIRATORY TRACT. The application comprises a 5-page
specification, including 5 claims and Abstract.

Accompanying this application for filing is:

Filing Fee: Small Entity, \$75.00 Large Entity, \$150.00

Check No. 37756, in the amount of \$ 150.00, is enclosed to cover
the Filing Fee. The Commissioner is hereby authorized to charge
payment of any fees set forth in §§1.16 or 1.17 during the pendency
of this application, or credit any overpayment, to Deposit Account
No. 06-1358. A duplicate copy of this sheet is enclosed.

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Respectfully submitted,

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By *William E. Player*
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Povidone iodine for the administration
via the upper and lower respiratory tract

The invention is concerned with the use of povidone iodine for administration via the upper and/or lower respiratory tract.

Povidone iodine is an antiseptic agent which is known for the topical treatment of infectious maladies. Also antibiotic agents are used for treatment of infectious diseases. A decisive disadvantage of antibiotic agents is that resistances are established, furthermore, antibiotics may sensitize the patients so that they develop allergies against such agents. Polividone iodine or PVP iodine, i. e. poly(1-vinyl-2-pyrrolidine-2-one)-iodine complex is an antiseptic agent which does not cause resistances of the infectious agents against that particular compound.

At present, infectious diseases of the respiratory tract are treated with antibiotics. This leads to the complications which are known to the skilled person. For example, patients suffering from chronical bronchitis are often treated with antibiotics in order to alleviate the symptoms. However, this

often merely leads to resistances of the bacteria which are responsible for the symptoms. Such patients are not cured from the infections.

It is one object of the present invention to avoid the drawbacks of the treatment of the respiratory tract using antibiotics.

Surprisingly, the use of povidone iodine into the upper and/or lower respiratory tract is able to treat diseases which are susceptible to the administration of povidone iodine via the upper and/or lower respiratory tract.

Preferably, the povidone iodine is prepared in form of a liposome preparation, in form of a microsphere preparation and/or in form of nanoparticle preparation.

The povidone iodine preparation can be administered to the respiratory tract by nebulization of the liposome, microsphere or nanoparticle preparation or by dry powder inhalation of the respective preparation. For example, a liposome preparation can be made by loading liposomes with PVP iodine in a conventional procedure. The nature or constitution of the liposomes are not critical. The liposome preparation as, for example, described in EP-A-0 639 373 'Al can be administered by inhalation of an aerosol. The disclosure of EP-A-0 639 373 is incorporated by reference. It is also possible to press the loaded liposomes, optionally together with auxiliary material such as low molecular sugars, preferably lactose, to a tightly compacted solid medicament stock. This medicament stock can then be abraded or micronized or treated in another way to yield the powder in particle form. Preferably, the particle sizes are in the range of 0.1 to 50 μm if inhaled to the lower respiratory tract or 1 to 50 μm when applied through nasal application.

The pressure for preparing the tightly compacted solid medicament stock are preferably in the range of from 50 to 500 MPa. Such medicament stock is described in WO 94/14490 and in device for administration is disclosed in WO 93/24165. The disclosure of WO 94/14490 and WO 93/24165 are incorporated by reference.

Instead of liposome preparations, it is also possible to associate the povidone iodine with nanoparticles or microspheres.

The present invention is useful in the treatment of infectious diseases or for alleviation of diseases such as HIV infections which are accompanied with opportunistic infections. Also patients having a suppressed immune system, for example, after organ transplants, can be treated according to the invention. In particular, acute and chronic bronchitis, pneumonia, bronchiectasia, cystic fibrosis, diphtheria, tuberculosis can be treated with the povidone iodine preparation according to the invention.

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Claims

1. Use of povidone iodine for the preparation of a pharmaceutical composition for the treatment of diseases which are susceptible to the administration of povidone iodine via the upper and/or lower respiratory tract.
2. Use according to claim 1 wherein the povidone iodine is prepared in form of a liposome preparation, in form of a microsphere preparation and/or in form of a nanoparticle preparation.
3. Use according to claim 1 and/or 2 wherein the administration of the povidone iodine preparation into the respiratory tract is performed by aerosol nebulization or by dry powder inhalation.
4. Use according to claim 1 for the treatment of infectious diseases or alleviation of diseases such as HIV-infections which are accompanied with opportunistic infections or with a suppressed immune system.
5. Use according to claim 1 for the treatment of acute and chronic bronchitis, pneumonia, bronchiectasia, cystic fibrosis, diphtheria, and/or tuberculosis.

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Abstract

Use of povidone iodine for the preparation of a pharmaceutical composition for the treatment of diseases which are susceptible to the administration of povidone iodine via the upper and/or lower respiratory tract.

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